K094645



## 510(k) Summary of Safety and Effectiveness

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APR 22 2010

**Date Prepared:** April 12, 2010

**Device:** Cardo Medical Hip System

**Classification:** 87 LPH and 87 HWC - Hip joint metal/polymer/metal semi-constrained uncemented prosthesis, 21 CFR 888.3358 Class II

**Predicate Devices:** Accin™ Hip System (now Cardo Medical Hip System) - K073068
Exactech 12/14 Total Hip System (Exactech, Inc.) – K041906, K993082

**Device Description:** The previously cleared Cardo Medical Hip System consists of

- commercially pure titanium plasma spray-coated titanium alloy (Ti-6Al-4V) femoral stems,
- cobalt chrome (CoCr) femoral heads
- commercially pure titanium plasma spray-coated titanium alloy (Ti-6Al-4V) acetabular shells
- ultra-high molecular weight polyethylene (UHMWPE) acetabular inserts and
- titanium alloy (Ti-6Al-4V) bone screws.

The proposed devices are a line extension to the previously cleared system to add 36mm femoral heads and 36mm inserts.

**Intended Use:** The Cardo Medical Hip System components are for use in total hip arthroplasty as a result of:

- Hip arthritis caused by rheumatoid disease, non-inflammatory degenerative joint disease, osteoarthritis, and arthritis resulting from biologic or mechanical trauma to the hip
- Correction of functional deformity
- Avascular Necrosis
- Treatment of non-unions, femoral neck and trochanteric fractures of the proximal femur
- Difficult clinical management problems involving persistent pain and physical impairment where conventional arthodesis is not likely to achieve satisfactory results

These components are single use only and are intended for implantation without bone cement.

**Comparison to Predicates:**

The proposed devices are a line extension to add 36mm femoral heads and inserts.

*Femoral Stems*
There has been **no change** to the existing femoral stems, available in 21 sizes from 6mm to 22.5mm with a regular or lateral offset. The stems are gamma irradiated.

*Femoral Heads*
The proposed 36mm cobalt chrome femoral heads have the same 12/14 trunnion taper as the previously cleared femoral heads, offered in sizes 22, 26, 28 and 32 mm OD in a variety of offsets (K073068). The 36mm femoral head will have offsets of -5, -3.5, 0, +3.5 and +5mm. The prior offsets ranged from -3.5 to +12mm with the +12mm being the worst case. The heads are gamma sterilized.

The proposed 36mm heads are equivalent to the Accin Hip System (K073068) in materials, design, packaging, and sterilization and equivalent to the Exactech 12/14 total hip system femoral heads in size.

*Acetabular Shells*
There has been **no change** to the existing acetabular shells. They are designed to mate with the acetabular inserts with a permanently inserted retaining ring and have three clustered holes for bone screws, if necessary. Each shell has a size that matches it to the correct inserts and are gamma sterilized.

*Acetabular Inserts*
The proposed 36mm UHMWPE acetabular inserts are a line extension to the previously cleared Accin inserts (K073068). The prior inserts are offered in standard and 10° hooded variations. The proposed 36mm insert will be offered in standard only. The prior inserts are available in 22mm, 26mm, 28mm, and 32mm inner diameter sizes. They are designed to mate with the previously cleared acetabular shells. Each liner has a size designation that matches it to the correct mating shell component. The new 36mm acetabular liners are designed to articulate with the proposed 36mm Cardo Medical cobalt chrome femoral heads. The inserts are gamma sterilized.

The proposed 36mm inserts are equivalent to the Accin Hip System (K073068) in materials, design, packaging and sterilization and equivalent to the Exactech 12/14 total hip system inserts in ID and OD.

*Bone Screws*
There has been **no change** to the existing titanium alloy bone screws cleared in K073068, which are in a 6.5mm diameter, in eight (8) lengths from 15mm to 60mm. The screws are gamma sterilized.

*Summary*
Cardo Medical, Inc. has determined that any differences in the proposed device will not impact the safety or effectiveness of the hip system for its intended use. Testing has shown that the proposed device meets the requirements of the current FDA Guidance documents on total hip arthroplasty product and the proposed device is equivalent to the predicate device.

All Cardo medical implant components are provided as sterile, single use only to a sterility assurance level (SAL) of $10^{-6}$.

**Synopsis of Test Methods and Results:**
This 510(k) is for the addition of 36mm femoral heads and inserts. These heads and inserts do not change the worst case products for testing purposes ( the 28mm femoral head component with the +12mm offset); therefore the previous testing applies to these components.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

APR 22 2010

Cardo Medical, Inc.
% Mr. Mike Kvitnitsky
Chief Operating Officer and President
10 Clifton Boulevard, Suite B1
Clifton, New jersey 07011

Re: K094045
Trade/Device Name: Cardo Medical Hip System
Regulation Number: 21 CFR 888.3358
Regulation Name: Hip Joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis
Regulatory Class: II
Product Code: LPH, HWC
Dated: February 11, 2010
Received: February 16, 2010

Dear Mr. Kvitnitsky:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

## Indications for Use Form

510(k) Number (if known): K094045

Device Name: Cardo Medical Hip System

Indications for Use:
The Cardo Medical Hip System components are for use in total hip arthroplasty as a result of:

- Hip arthritis caused by rheumatoid disease, non-inflammatory degenerative joint disease, osteoarthritis, and arthritis resulting from biologic or mechanical trauma to the hip
- Correction of functional deformity
- Avascular Necrosis
- Treatment of non-unions, femoral neck and trochanteric fractures of the proximal femur
- Difficult clinical management problems involving persistent pain and physical impairment where conventional arthodesis is not likely to achieve satisfactory results

These components are single use only and are intended for implantation without bone cement.

Prescription Use X (Per 21 CFR 801.109) OR Over-The-Counter Use (Optional Format 1-2-96)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K094045